K100610 Pg 1 of 5

510(k) Summary for the
Lutronic Corporation eCO2 Plus, DENTA III, SP III Laser Systems

JAN 20 2011

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990, 21 CFR 807.92, and 21 CFR 878.4810.

1. **General Information**

Submitter:	Lutronic Corporation #403-2,3,4, Ilsan Technotown 1141-1 Baeksok-Dong, Ilsan-Gu Goyang-Si, Gyeonggi-Do, 410-722 Republic of Korea
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-824-2541
Summary Preparation Date:	January 19, 2011

2. **Names**

Device Name:	eCO2 Plus Laser System DENTA III Laser System DENTA III+ Laser System SP III Laser System
Classification Name:	Powered Laser Surgical Instrument With Microbeam\Fractional Output Laser Instrument, Surgical, Powered Product Code: ONG GEX Panel: General & Plastic Surgery Regulation number: 21 CFR 878.4810

3. **Predicate Devices**

The eCO2 Plus, DENTA III, DENTA III+ and SP III Laser Systems are substantially equivalent to a combination of the Lutronic Corporation eCO2 Laser System (K091115) and the Lutronic Corporation Spectra SP II and Spectra DENTA II Laser Systems (K091320).

4. Device Description

The eCO2 Plus, SP III, DENTA III and DENTA III+ Laser Systems utilize a CO2 RF module to generate a laser beam with a wavelength of 10.6 um and use different handpiece for different indications for use. The physician can optimize the effect for different applications by controlling the power of the laser pulse and using a different handpiece. The Laser Systems are supplied with different handpieces depending upon the device configuration.

5. Indications for Use

The eCO2 Plus Laser System with fractionated handpieces is indicated for use in dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue. Additionally, the 120 micron and 300 micron spot sizes are used in the treatment of wrinkles; rhytides, furrows, fine lines, textural irregularities, pigmented lesions and vascular dyschromia.

The eCO2 Plus Laser System using the non-fractionated handpieces (F100, F50, and Zoom) is also indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology (ENT), arthroscopy, (knee), and open endoscopic general surgery.

Dermatology & Plastic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- Laser skin resurfacing
- Treatment of wrinkles, rhytids and furrows
- Ablation and/or vaporization of soft tissue in dermatology and plastic surgery for the reduction, removal, and/or treatment of actinic keratosis, skin tags, solar/actinic elastosis, actinic cheilitis, lentigines, uneven pigmentation/dyschromia, acne scars, surgical scars, keloids, hemangiomas (including buccal hemangiomas), tattoos, telangiectasia, squamous and basal cell carcinoma, spider and epidermal naevi, xanthelasma palpebrarum, syringoma, and verrucae and seborrhoecae vulgares (warts); laser derm-ablation; and laser burn debridement.

Dermatology, Plastic Surgery & General Surgery
Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery, including the performance of blepharoplasty and for the creation of recipient sites for hair transplantation, treatment of hemorrhoids, atheroma, cysts, abscesses, and all other soft tissue applications.

Podiatry
Laser ablation, vaporization, and/or excision of soft tissue in podiatry for the reduction, removal, and/or treatment of verrucae vulgares, and matrixectomy.

Otorhinolaryngology (ENT)
Laser incision, excision, ablation and/or vaporization of soft tissue in otorhinolaryngology for the treatment of choanal atresia, leukoplakia of larynx, nasal obstruction, UPP, rhinophyma, adult and juvenile papillomatosis polyps, rhinophyma and verrucae vulgares.

Gynecology
Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of cervical intraepithelial neoplasia, condyloma acuminata, leukoplakia (vulvar dystrophies) and vulvar and vaginal intraepithelial neoplasia.

Neurosurgery
Laser incision, excision, ablation and/or vaporization of soft tissue in neurology for the treatment of basal tumor-meningioma, posterior fossa tumors, peripheral neurectomy, and lipomas/large tumors.

The DENTA III Laser System using the non-fractionated handpieces (F100, F50, and Zoom) is indicated for use in soft tissue dental indications including periodontic procedures such as, but not limited to, removal of diseased or inflamed soft tissue in the periodontal pocket (sulcular debridement), vaporization, gingivectomy-removal of hyperplasias, gingivoplasty, papillectomy, vestibuloplasty, fibroma (nonmalignant tumor, mucosa, tongue), epulis, incision and excision, removal of soft tissue, cysts, and tumors, and laser assisted new attachment procedure (cementum-mediated periodontal ligament new attachment to the root surface in the absence of long junctional epithelium); Oral surgery such as frenectomy, frenum release, drainage (abscess), flap surgery, incisional and excisional biopsy, incision and excision of aphthous ulcers, incision of infection when used with antibiotic therapy, excision and ablation of benign and malignant lesions, oral cavity tumors and hemangiomas, salivary gland pathologies, preprosthetic gum preparation, leukoplakia; partial glossectomy, periodontal gum resection, homeostasis, operculectomy, and crown lengthening.

The DENTA III+ Laser System using fractionated handpieces is indicated for use in dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue. Additionally, the 120 micron and 300 micron spot sizes are used in the treatment of wrinkles; rhytides, furrows, fine lines, textural irregularities, pigmented lesions and vascular dyschromia.

The DENTA III+ Laser System using non-fractionated handpieces (F100, F50, and Zoom) is indicated for use in soft tissue dental indications including periodontic procedures such as, but not limited to, removal of diseased or inflamed soft tissue in the periodontal pocket (sulcular debridement), vaporization, gingivectomy-removal of hyperplasias, gingivoplasty, papillectomy, vestibuloplasty, fibroma (nonmalignant tumor, mucosa, tongue), epulis, incision and excision, removal of soft tissue, cysts, and tumors, and laser assisted new attachment procedure (cementum-mediated periodontal ligament new attachment to the root surface in the absence of long junctional epithelium); Oral surgery such as frenectomy, frenum release, drainage (abscess), flap surgery, incisional and excisional biopsy, incision and excision of aphthous ulcers, incision of infection when used with antibiotic therapy, excision and ablation of benign and malignant lesions, oral cavity tumors and hemangiomas, salivary gland pathologies, preprosthetic gum

preparation, leukoplakia; partial glossectomy, periodontal gum resection, homeostasis, operculectomy, and crown lengthening.

The SP III Laser System using the non-fractionated handpieces (F100, F50, and Zoom) is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology (ENT), arthroscopy, (knee), and open endoscopic general surgery.

Dermatology & Plastic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- Laser skin resurfacing
- Treatment of wrinkles, rhytids and furrows
- Ablation and/or vaporization of soft tissue in dermatology and plastic surgery for the reduction, removal, and/or treatment of actinic keratosis, skin tags, solar/actinic elastosis, actinic cheilitis, lentigines, uneven pigmentation/dyschromia, acne scars, surgical scars, keloids, hemangiomas (including buccal hemangiomas), tattoos, telangiectasia, squamous and basal cell carcinoma, spider and epidermal naevi, xanthelasma palpebrarum, syringoma, and verrucae and seborrhoecae vulgares (warts); laser derm-ablation; and laser burn debridement.

Dermatology, Plastic Surgery & General Surgery
Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery, including the performance of blepharoplasty and for the creation of recipient sites for hair transplantation, treatment of hemorrhoids, atheroma, cysts, abscesses, and all other soft tissue applications.

Podiatry
Laser ablation, vaporization, and/or excision of soft tissue in podiatry for the reduction, removal, and/or treatment of verrucae vulgares, and matrixectomy.

Otorhinolaryngology (ENT)
Laser incision, excision, ablation and/or vaporization of soft tissue in otorhinolaryngology for the treatment of choanal atresia, leukoplakia of larynx, nasal obstruction, UPP, rhinophyma, adult and juvenile papillomatosis polyps, rhinophyma and verrucae vulgares.

Gynecology
Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of cervical intraepithelial neoplasia, condyloma acuminata, leukoplakia (vulvar dystrophies) and vulvar and vaginal intraepithelial neoplasia.

Neurosurgery
Laser incision, excision, ablation and/or vaporization of soft tissue in neurology for the treatment of basal tumor-meningioma, posterior fossa tumors, peripheral neurectomy, and lipomas/large tumors.

6. Performance Data
None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lutronic Corporation
% O'Connell Regulatory Consultants, Inc.
Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

JAN 2 0 2011

Re: K100610
Trade/Device Name: eCO_2 Plus Laser System
Fractionated and Non-Fractionated Handpieces;
DENTA III Laser System - Non-Fractionated Handpieces;
DENTA III+ Laser System
Fractionated and Non-Fractionated Handpieces;
SP III Laser System - Non-Fractionated Handpieces
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONG, GEX
Dated: January 03, 2011
Received: January 04, 2011

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100610

Device Name: eCO2 Plus Laser System-Fractionated Handpieces

Indications for Use:

The eCO2 Plus Laser System with fractionated handpieces is indicated for use in dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue. Additionally, the 120 micron and 300 micron spot sizes are used in the treatment of wrinkles; rhytides, furrows, fine lines, textural irregularities, pigmented lesions and vascular dyschromia.

Neil R P Ogden for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100610

Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

K100610

Indications for Use

510(k) Number (if known): _____

Device Name: eCO2 Plus Laser System-Non-Fractionated Handpieces

Indications for Use:

The eCO2 Plus Laser System using the non-fractionated handpieces (F100, F50, and Zoom) is also indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology (ENT), arthroscopy, (knee), and open endoscopic general surgery.

Dermatology & Plastic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- Laser skin resurfacing
- Treatment of wrinkles, rhytids and furrows
- Ablation and/or vaporization of soft tissue in dermatology and plastic surgery for the reduction, removal, and/or treatment of actinic keratosis, skin tags, solar/actinic elastosis, actinic cheilitis, lentigines, uneven pigmentation/dyschromia, acne scars, surgical scars, keloids, hemangiomas (including buccal hemangiomas), tattoos, telangiectasia, squamous and basal cell carcinoma, spider and epidermal naevi, xanthelasma palpebrarum, syringoma, and verrucae and seborrhoecae vulgares (warts); laser derm-ablation; and laser burn debridement.

Dermatology, Plastic Surgery & General Surgery
Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery, including the performance of blepharoplasty and for the creation of recipient sites for hair transplantation, treatment of hemorrhoids, atheroma, cysts, abscesses, and all other soft tissue applications.

Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Dyke for mkm
(Division Sign-Off) Page 2 of 8
Division of Surgical, Orthopedic,
and Restorative Devices

Podiatry
Laser ablation, vaporization, and/or excision of soft tissue in podiatry for the reduction, removal, and/or treatment of verrucae vulgares, and matrixectomy.

Otorhinolaryngology (ENT)
Laser incision, excision, ablation and/or vaporization of soft tissue in otorhinolaryngology for the treatment of choanal atresia, leukoplakia of larynx, nasal obstruction, UPP, rhinophyma, adult and juvenile papillomatosis polyps, rhinophyma and verrucae vulgares.

Gynecology
Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of cervical intraepithelial neoplasia, condyloma acuminata, leukoplakia (vulvar dystrophies) and vulvar and vaginal intraepithelial neoplasia.

Neurosurgery
Laser incision, excision, ablation and/or vaporization of soft tissue in neurology for the treatment of basal tumor-meningioma, posterior fossa tumors, peripheral neurectomy, and lipomas/large tumors.

Prescription Use X___ AND/OR Over The Counter Use _____
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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
and Restorative Devices

K100610

Indications for Use

510(k) Number (if known): _____

Device Name: DENTA III Laser System-Non-Fractionated Handpieces

Indications for Use:

The DENTA III Laser System using the non-fractionated handpieces (F100, F50, and Zoom) is indicated for use in soft tissue dental indications including periodontic procedures such as, but not limited to, removal of diseased or inflamed soft tissue in the periodontal pocket (sulcular debridement), vaporization, gingivectomy-removal of hyperplasias, gingivoplasty, papillectomy, vestibuloplasty, fibroma (nonmalignant tumor, mucosa, tongue), epulis, incision and excision, removal of soft tissue, cysts, and tumors, and laser assisted new attachment procedure (cementum-mediated periodontal ligament new attachment to the root surface in the absence of long junctional epithelium); Oral surgery such as frenectomy, frenum release, drainage (abscess), flap surgery, incisional and excisional biopsy, incision and excision of aphthous ulcers, incision of infection when used with antibiotic therapy, excision and ablation of benign and malignant lesions, oral cavity tumors and hemangiomas, salivary gland pathologies, preprosthetic gum preparation, leukoplakia; partial glossectomy, periodontal gum resection, homeostasis, operculectomy, and crown lengthening.

Prescription Use X AND/OR Over The Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100610

K100610

Indications for Use

510(k) Number (if known): _____

Device Name: DENTA III+ Laser System-Fractionated Handpieces

Indications for Use:

The DENTA III+ Laser System using fractionated handpieces is indicated for use in dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue. Additionally, the 120 micron and 300 micron spot sizes are used in the treatment of wrinkles; rhytides, furrows, fine lines, textural irregularities, pigmented lesions and vascular dyschromia.

Prescription Use X AND/OR Over The Counter Use _____
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nick RP Ogden for MKM
Page 5 of 8
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

K100610

Indications for Use

510(k) Number (if known): _____

Device Name: DENTA III+ Laser System-Non-Fractionated Handpiece

Indications for Use:

The DENTA III+ Laser System using non-fractionated handpieces (F100, F50, and Zoom) is indicated for use in soft tissue dental indications including periodontic procedures such as, but not limited to, removal of diseased or inflamed soft tissue in the periodontal pocket (sulcular debridement), vaporization, gingivectomy-removal of hyperplasias, gingivoplasty, papillectomy, vestibuloplasty, fibroma (nonmalignant tumor, mucosa, tongue), epulis, incision and excision, removal of soft tissue, cysts, and tumors, and laser assisted new attachment procedure (cementum-mediated periodontal ligament new attachment to the root surface in the absence of long junctional epithelium); Oral surgery such as frenectomy, frenum release, drainage (abscess), flap surgery, incisional and excisional biopsy, incision and excision of aphthous ulcers, incision of infection when used with antibiotic therapy, excision and ablation of benign and malignant lesions, oral cavity tumors and hemangiomas, salivary gland pathologies, preprosthetic gum preparation, leukoplakia; partial glossectomy, periodontal gum resection, homeostasis, operculectomy, and crown lengthening.

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Neil R Ogden for mm
~~Page 6 of 8~~
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Division of Surgical, Orthopedic,
and Restorative Devices

K100610

Indications for Use

510(k) Number (if known): _____

Device Name: SP III Laser System-Non-Fractionated Handpieces

Indications for Use:

The SP III Laser System using the non-fractionated handpieces (F100, F50, and Zoom) is indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: dermatology, plastic surgery, podiatry, neurosurgery, gynecology, otorhinolaryngology (ENT), arthroscopy, (knee), and open endoscopic general surgery.

Dermatology & Plastic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

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Dermatology, Plastic Surgery & General Surgery
Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery, including the performance of blepharoplasty and for the creation of recipient sites for hair transplantation, treatment of hemorrhoids, atheroma, cysts, abscesses, and all other soft tissue applications.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Ryan for mkm
(Division Sign-Off) ~~Page 7 of 8~~
Division of Surgical, Orthopedic,
and Restorative Devices

K100610

Podiatry
Laser ablation, vaporization, and/or excision of soft tissue in podiatry for the reduction, removal, and/or treatment of verrucae vulgares, and matrixectomy.

Otorhinolaryngology (ENT)
Laser incision, excision, ablation and/or vaporization of soft tissue in otorhinolaryngology for the treatment of choanal atresia, leukoplakia of larynx, nasal obstruction, UPP, rhinophyma, adult and juvenile papillomatosis polyps, rhinophyma and verrucae vulgares.

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Laser incision, excision, ablation and/or vaporization of soft tissue in gynecology for the treatment of cervical intraepithelial neoplasia, condyloma acuminata, leukoplakia (vulvar dystrophies) and vulvar and vaginal intraepithelial neoplasia.

Neurosurgery
Laser incision, excision, ablation and/or vaporization of soft tissue in neurology for the treatment of basal tumor-meningioma, posterior fossa tumors, peripheral neurectomy, and lipomas/large tumors.

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510(k) Number K100610